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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,235	03/17/2004	Elizabeth Dzcng	Stanford S03-060	5638

39843 7590 06/16/2006

BELL & ASSOCIATES  
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SAN FRANCISCO, CA 94118

EXAMINER
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GIBSON, ROY DEAN

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/803,235

Applicant(s)

DZENG ET AL.

Examiner

Roy D. Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13, 14 and 16-36 is/are rejected.
- 7) ☐ Claim(s) 10, 11 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/17/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/17&11/05/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the ultrasound transducer of claim 10 and the digestible composition of claim 11 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Note: element numbers for the above should also be added to the Specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 8-9, 13-14 and 22-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Saab (5,624,392).

As to claims 1, 2 and 9, Saab discloses a heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising:

(a) a first elongate tubular body (Figure 3, # 66) having a proximal end and a distal end,

(b) a second elongate tubular body (62) having a proximal end and a distal end, and

(c) a balloon (70) defining a lumen (64) in fluid communication with both the first elongate tubular body and the second elongate tubular body so as to form a continuous fluid pathway, and wherein the balloon, when inflated, is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the

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balloon, and whereby inherently a target organ adjacent to the anatomical structure is thereby cooled (col. 11, line 62-col. 12, line 67).

As to claims 3, 4 and 8, Saab further discloses a thermal exchange composition within the balloon lumen and wherein the thermal exchange composition flows within the continuous fluid (liquid) pathway formed by the second elongate tubular body, the first elongate tubular body, and the balloon lumen (Figure 3).

As to claim 6, Saab further discloses the heat exchange catheter system wherein the balloon is shaped and sized for placement in the anatomical structure selected from the group consisting of: the venous system.

As to claims 13 and 14, Saab further discloses the heat exchange catheter system of claim 1 further comprising a third elongate tubular body (74) having a proximal end and a distal end, the third elongate tubular body disposed longitudinally within the second elongate tubular body, and wherein the balloon is sealably affixed to the outer surface of the first elongate tubular body and sealably affixed to the outer surface of the third elongate tubular body, and further comprising a guidewire (Figure 1, # 11) disposed within third elongate tubular body (74) (col. 7, line 58-col. 10, line 23).

As to claims 22-29, Saab discloses all elements of these claims as presented above, where the saccular body is the balloon (70) which forms a flexible and elastic reservoir.

Claims 1-9, 13, 14 and 22-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Lalonde et al. (6,283,959).

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As to claim 1-9 and 13-14, Lalonde et al. disclose in Figure 9B, all elements of these claims and that the device may be applied to cool the esophagus where inherently the heart will be cooled also by circulating of a gas or a liquid and positioned by guidewire (221) placed within the third elongate member or lumen (Figure 9B and col. 4, lines 7-12 and col. 10, line 38-col. 11, line 34).

As to claims 22-30, Lalonde et al. disclose all elements of these claims as presented above, where the saccular body is the balloon which forms a flexible and elastic reservoir. Also an option for the coolant, liquid saline is provided by a pump (claim 30 limitation).

As to claims 31-34, Lalonde et al. disclose all the steps essentially as claimed which would be inherent when the esophagus is cooled thus cooling the adjacent heart.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-21 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lalonde et al. Although Lalonde et al. fail to disclose the specific cooling rates claimed, the examiner maintains that even the most rapid rate of 2-5 deg./30 minutes can be realized by the catheter system based on typical performance of the disclosed coolants.

***Allowable Subject Matter***

Claims 10-12 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

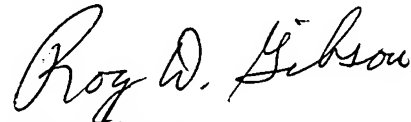
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink that reads "Roy D. Gibson". The signature is written in a cursive, flowing style.

Roy D. Gibson  
Primary Examiner  
Art Unit 3739

June 12, 2006